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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,400	02/02/2007	Zoser B. Salama	7014-110	8658
46/02 7590 05/14/2008 JOYCE VON NATZMER PIQUIGNOT + MYERS LLC 200 Madison Avenue Suite 1901 New York, NY 10016				
EXAMINER NAZARIO GONZALEZ, FORTRIO				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
05/14/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,400

Applicant(s)

SALAMA, ZOSER B.

ExaminerPORFIRIO NAZARIO
GONZALEZ**Art Unit**

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-9 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9 and 11-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/2/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of tumors, does not reasonably provide enablement for the prophylaxis, therapy, follow-up and aftercare of diseases associated with cell-growth, cell differentiation and/or cell division. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.
4. For a rejection under 35 U.S.C. § 112, first paragraph the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of the claims
- 2) Nature of the invention
- 3) State of the prior art
- 4) Level of ordinary skill in the art
- 5) Level of predictability in the art
- 6) Amount of direction and guidance provided by the inventor

7) Existence of working examples

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claims involves the preparation of a platinum(IV) complexes and their use as therapeutic agents. The nature of the invention is in the field of platinum chemistry.

The state of the art shows the preparation of platinum(IV) complexes and their anticancer activity. Particularly, the prior art shows the preparation of *cis,trans,cis*-[Pt Cl₂(OH)₂(NH₃)₂] and *cis,trans,cis*-[Pt Cl₂(OAc)₂(NH₃)₂] and their use as anti-tumor agents. See, Hall et al., J. Bio. Inorg. Chem., Vol. 8, pp. 726-732 (2003). The level of ordinary skill in the arts is high and limited to the preparation and use of anti-tumor Pt(IV) complexes.

The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to the preparation of platinum(IV) complexes and their use against a series of cancer cell lines. See Tables 1-5. No examples are provided for the use of the claimed Pt(IV) complexes against diseases associated with cell-growth, cell differentiation and/or cell division other than cancer. Here, using the anti-tumor data to extrapolate such results to support the use of the

claimed Pt(IV) complexes in other therapies other than cancer is not proper since the mode of action of Pt(IV) complexes against tumors does not necessarily would be the same against other diseases. Furthermore, the instant specification fails to provide evidence of prophylaxis, that is, prevention of a particular disease by administering the claimed Pt(IV) complexes to a healthy patient.

Therefore, the quantity of experimentation required to use the compounds as claimed, based on applicant's limited disclosure would be undue burden because one of ordinary skill in the art would have to perform a significant amount of experimentation to ascertain how to use the claimed compounds in other therapies other than cancer therapy.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 6-9, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear to the examiner how the general formula in claim 2 can be a neutral compound when X_1 and X_2 is either calcium or magnesium ions. Please clarify. As for claim 1, the recited process does not produces *trans*- or *cis*-diammoniumdichlorodihydroxoplatinum(IV) but rather a derivative of said compound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PORFIRIO NAZARIO GONZALEZ whose telephone

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number is (571)272-0641. The examiner can normally be reached on Mon.-Fri. (9:30 AM - 6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Porfirio Nazario-Gonzalez/
Primary Examiner
Art Unit 1621

PNG
May 7, 2008